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AXINN, VELTROP & HARKRIDER LLP			EXAMINER	
Attn. Michael A. Davitz			LIU, SUE XU	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/536,569	Applicant(s) WIESNER ET AL.
	Examiner SUE LIU	Art Unit 1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 September 2008.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 14, 16, 17 and 22-38 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 14, 16, 17 and 22-38 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/06)
 Paper No(s)/Mail Date 0/20/06; 2/28/06.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Claim Status

1. Claims 1-13, 15 and 18-21 have been cancelled as filed on 9/25/08.

Claims 14, 16, 17 and 22-38 are currently pending.

Claims 14, 16, 17 and 22-38 are being examined in this application.

Election/Restrictions

2. Upon further consideration, the previous set forth requirement for Species Election (mailed 6/25/08) is withdrawn.

Priority

3. This application is filed under 35 U.S.C 371 of PCT/US03/37963 (filed on 11/26/2003), which claims priority as a CIP of US patent application 10/306,614 (filed on 11/26/2002).

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35

U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/306,614 (hereinafter referred to as the ‘614 application), fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

The instant claims 14, 26 and 34 have been added and/or amended as filed on 9/25/08. However, the ‘614 application does not provide support for the claimed “fluorescent nanoparticle”. In particular, the ‘614 application as originally filed do not disclose fluorescent nanoparticles having diameter ranges of “about 4 nm to about 150 nm” and “between about 10.0 nanometers and about 150.0 nanometers” as well as the core having about 10 to 200 nm or the shells having diameters of 25 to 500 nm. Similarly, the ‘614 application also does not provide support for the instant claimed ranges of “about 4 nm to about 10 nm”; “between about 10.0 nanometers and 25 nanometers”; etc., as recited in the instant claims 16, 28, 29 and 35. The instant claim 24 recites a specific ratio range of about 1:1 to 1:10, which also does not have support in the ‘614 application.

The instant claims 25 and 30 recite “at least 25% greater than the fluorescent quantum yield”, which also does not have support in the ‘614 application.

The instant claim 27 recites specific structures for the silica based core, which also does not have support in the ‘614 application.

The instant claim 33 recite “wherein the mercapto group is bonded to a maleimide” which does not have support in the ‘614 application.

Thus, the instant claims 14, 16, 17 and 22-38 do not obtain the benefit of the earlier filed '614 application. The effective filing date for the instant claims 14, 16, 17 and 22-38 is 11/26/2003.

Information Disclosure Statement

5. The IDS filed on 6/20/06 has been considered. See the attached PTO 1449 forms.

The information disclosure statement filed 6/20/06 (page 2) fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered. In the "Supplemental Information Disclosure Statement" filed on 6/20/06 (page 2), applicants listed two references. The first reference (Ow et al) does not appear to be listed in the IDS form, and it is also not clear if a copy of the said reference was provided. The said Ow reference is, thus, not considered.

6. The IDS filed on 2/28/06 has been considered. See the attached PTO 1449 form. However, the reference listed with document code "H" is not considered due to the missing date

information. In addition, applicants are also advised to notice the inserted date information for documents with codes A, B, E and F. Applicants are reminded that the date information is needed for each cited reference in IDS.

Oath/Declaration

7. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). See the last page of the Oath/Declaration.

Specification

8. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. MPEP 608.01.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter Rejection

10. Claims 14, 16, 17 and 22-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 14, 26 and 34 have been added and/or amended as filed on 9/25/08. However, the instant specification does not provide support for the claimed “fluorescent nanoparticle”. In particular, the instant specification and claims as originally filed do not disclose fluorescent nanoparticles having diameter ranges of “about 4 nm to about 150 nm” and “between about 10.0 nanometers and about 150.0 nanometers” as well as the core having about 10 to 200 nm or the shells having diameters of 25 to 500 nm. Similarly, the instant specification also does not provide support for the instant claimed ranges of “about 4 nm to about 10 nm”; “between about 10.0 nanometers and 25 nanometers”; etc., as recited in the instant claims 16, 28, 29 and 35. The instant claim 24 recites a specific ratio range of about 1:1 to 1:10, which also does not have support in the instant specification.

The instant claims 25 and 30 recite “at least 25% greater than the fluorescent quantum yield”, which also does not have support in the instant specification.

The instant claim 27 recites specific structures for the silica based core, which also does not have support in the instant specification.

If Applicant believes this rejection is in error, applicant must disclose where in the specification support for the entire scope of the amendment(s) and/or new claims can be found. As a result, Claims 14, 16, 17 and 22-38 represent new matter.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Graf

12. Claims 14, 16, 17, 22-28 and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by **Graf** et al (Langmuir. Vol.15: 6170-6180; 1999; cited in IDS).

The instant claims recite “A fluorescent nanoparticle comprising a fluorescent organic dye covalently conjugated to an organo-silane compound, wherein the fluorescent nanoparticle is conjugated to a ligand and has a diameter from about 4 nm to about 150 nm.”

Graf et al, throughout the publication, teach dye labeled silica based particles with “core-shell” structure with radius about 10 nm (e.g. Abstract). The reference teaches silica nanoparticles (e.g. Figure 1) with silica core and silica shell and functional groups for attaching various organic fluorescent dyes to the silica core or within the silica core (e.g. Figure 1; Figure 2), which reads on the nanoparticle of **claims 14 and 26** as well as the particle shell as recited in **claim 23**. The instant specification does not specifically define the term “ligand” to comprise a

particular structure. The dictionary defines the term “ligand” as “a group, ion, or molecule coordinated to a central atom or molecule in a complex” (see Definition for “Ligand” downloaded from Merriam-Webster Online Dictionary; downloaded on 12/10/08). Thus, the term “ligand” broadly encompasses the various chemical groups. The reference teaches the silica shell of the nanoparticles are formed with chemical groups of poly(organosiloxane), which any of the chemical groups on the shell read on a ligand as recited in **clms 14 and 26** as well as the external surface of **clms 17, 32 and 37**.

The reference also teaches various functional groups can be used for linking dyes to the silica nanoparticles including “(CH₂)₃SH” (a mercapto group) (e.g. p.6170, left col.), which read on the mercapto group of **clms 22, 26 and 38**. The reference also teaches the size of the particle is about 10 nm in range (e.g. p.6179, last para), which read on the size recited in **clms 14, 16, 26, 28,**

The reference also teaches various sizes for the core and the shell portion of the nanoparticles (e.g. Table 2), which reads on the ratios recited in **clm 24**.

Although the cited references do not explicitly teach the specific fluorescent quantum yield as recited in **clms 25 and 30**, the fluorescent quantum yield is an inherent property of the nanoparticles. As discussed supra, the nanoparticles of the references’ teachings have been demonstrated to be structurally the same as the instant claimed nanoparticles, the nanoparticles of the references would inherently possess the same property.

The reference teaches the nanoparticles comprising at least “trimethoxy(chlorobenzyl)silane” and coupling the fluorescent dye to the chlorobenzyl functional group (e.g. Figure 1 and caption; Figure 2), which the dye attached structure read on

the structure of **clm 27** with R2=Me group, and R1 = the fluorescent dye group. The reference's teachings also read on the organic fluorescent compound and covalent conjugation as recited in **clm 31 and 36**.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Graf and Amiche

15. Claims **14, 16, 17, 22-32** and **34-38** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Graf et al** (Langmuir. Vol.15: 6170-6180; 1999; cited in IDS), in view of **Amiche** (US 6,132,773; 10/17/2000) and if necessary in view of **van Blaaderen et al** (Langmuir. Vol.8: 2921-2931; 1992; cited in IDS).

Graf et al, throughout the publication, teach dye labeled silica based particles with "core-shell" structure with radius about 10 nm (e.g. Abstract) as discussed supra. The rejection over **Graf** under section 102(b) above is hereby incorporated by reference in its entirety.

Graf does not explicit teach the thickness of the silica shell as recited in **clm 29, 34** and **35.**

However, **Amiche** teach generating silica particles with shell thickness of 2 to 200 nm or 5 to 50 nm (e.g. col.4, lines 25+).

In addition, **van Blaaderen** et al teach “a layer of any desired thickness of silica can be deposited on the organosilica and coated-silica spheres” when generating silica particles with core-shell type of structure.

Therefore, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to generate silica based “core-shell” structured nanoparticles with various silica shell thicknesses such as 25 to 100 nm.

A person of ordinary skill in the art would have been motivated at the time of the invention to use silica based nanoparticles with silica shell of various thicknesses including 25nm to 50nm, because van Blaaderen teach generating silica core-shell type of particles with various silica shell thicknesses are routine and known in the art and the Amiche reference teaches silica shell with thickness in the range of 5 to 50 nm (for example) is known and routine in the art. In addition, because both the van Blaaderen and the Amiche references teach methods of using various nanoparticles with various silica shell thickness, it would have been obvious to one skilled in the art to substitute one type of silica shell thickness for the other to achieve the predictable result of detecting analytes in samples based on fluorescence silica nanoparticles. It would have been obvious to one of ordinary skill in the art to apply the standard technique of generating a silica core-shell nanoparticle with desired silica shell thickness, as taught by both

van Blaaderen and Amiche, to improve the nanoparticles (increase the silica shell thickness for the predictable result of enabling standard analyte detection method.

A person of ordinary skill in the art would have reasonable expectation of success of achieving such modifications since all of the techniques for generating the silica based nanoparticles with various functional groups (such as mercapto groups) for attaching fluorescent dyes and ligands, the techniques for using the various nanoparticles for analyte detection and the techniques for generating silica particles with various silica shell thickness are known and routine in the art as demonstrated by the cited references.

Graf and Others

16. Claims 14, 16, 17 and 22-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Graf** et al (Langmuir. Vol.15: 6170-6180; 1999; cited in IDS), **Amiche** (US 6,132,773; 10/17/2000) and **van Blaaderen** et al (Langmuir. Vol.8: 2921-2931; 1992; cited in IDS) as applied to claims 14, 16, 17, 22-32 and 34-38 above, and further in view of **Gu** et al. (PGPUB 20020048800; 4/25/2002).

The combination of the Graf, Amiche and van Blaaderen reference teach nanoparticles with attached fluorescent labels, as discussed supra. The teaching of the combination of the said references under section 103(a) above is hereby incorporated by reference in its entirety.

The combination of said references (Graf, Amiche and van Blaaderen) does not explicitly teach the mercapto group is bonded to a maleimide as recited in **clm 33**.

However, **Gu** et al, throughout the patent teaches various methods/reagents for fluorescently labeling biological molecules (e.g. p.25). The reference teaches “a wide variety of

Art Unit: 1639

amine-reactive and thiol-reactive fluorophore derivatives” can react with various groups including thiol groups (or mercapto groups) (e.g. [0347]). The reference also teaches various thiol-reactive fluorophores including “Alexa Fluor 488” are commercially available (e.g. [0348] +), which the “Alexa Fluor 488” inherently has “Maleimide” functional group fro reaction with the “thiol-reactive probes”, as evidenced by the “Material Safety Data Sheet” and “Manual for Thiol-Reactive Probes” from Invitrogen (Downloaded from Invitrogen.com; Downloaded on 12/10/08).

Therefore, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to generate silica based “core-shell” structured nanoparticles with attached label through a mercapto-maleimide linkage especially when using a maleimide functional group containing fluorescent dye.

A person of ordinary skill in the art would have been motivated at the time of the invention to use a maleimide functional containing dye to label nanoparticles, because Gu et al teach the convenience of using commercially available fluorescent dyes. In addition, it would have been obvious to a person of ordinary skill in the art to try the maleimide group containing fluorescent dye to label the nanoparticle of Graf through the mercapto (or thiol) functional group, to improve the labeling efficiency, as a person with ordinary skill has good reason to pursue the know options (such as either using amine-reactive or thiol-reactive labeling) within his or her technical grasp.

A person of ordinary skill in the art would have reasonable expectation of success of achieving such modifications since all of the techniques for attaching various fluorescent

molecules through various reactive groups (such as thiol reactive) are known and routine in the art as demonstrated by the cited references.

Graf and Others 2

17. Claims 14, 16, 17 and 22-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Graf** et al (Langmuir. Vol.15: 6170-6180; 1999; cited in IDS), in view of **Amiche** (US 6,132,773; 10/17/2000), **van Blaaderen** et al (Langmuir. Vol.8: 2921-2931; 1992; cited in IDS), and **Gu** et al. (PGPUB 20020048800; 4/25/2002), and if necessary in view **Weiss** et al (US 6,207,392; 3/27/2001; cited in IDS).

The combination of the Graf, Amiche, van Blaaderen and Gu referencees teach nanoparticles with attached fluorescent labels, as discussed supra. The teaching of the combination of the said references under section 103(a) above is hereby incorporated by reference in its entirety.

The combination of said references (Graf, Amiche and van Blaaderen) does not explicitly teach the ligand is a biological molecule if interpreting the instant claims narrowly.

However, **Weiss** et al, throughout the patent, teach using silica particles to detect the presence of substances (e.g. Abstract). The reference teaches conjugating affinity molecules (read on ligands) onto nanocrystals (or nanoparticles) (e.g. col.9, lines 15+; col.3, lines 45+). The reference also teaches nanoparticles having “mercapto” functional groups as linkers (e.g. col.11). The reference also teaches the ligands (or probes) and analytes (or detecting substances) are various biological molecules including proteins (such as antibodies) and DNA (e.g. col.9, lines 25+; col.12, lines 45+).

Therefore, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to generate silica based “core-shell” structured nanoparticles with attached biological molecules as ligands.

A person of ordinary skill in the art would have been motivated at the time of the invention to attach biological molecules (such as proteins) to fluorescent nanoparticles, because Weiss et al teach attaching ligands to nanoparticles is routine and known in the art and the attached nanoparticles offer the advantages of “a stable probe material for biological applications” (e.g. Weiss, col.2). In addition, because the cited references teach making various labeled nanoparticles with attached ligands for various purposes, it would have been obvious to one skilled in the art to substitute one type of ligand for the other to achieve the predictable result of generating detectable probes with the desired ligands.

A person of ordinary skill in the art would have reasonable expectation of success of achieving such modifications since all of the techniques for attaching various ligands to nanoparticles are known and routine in the art as demonstrated by the cited references.

Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

'614

19. Claims 14, 16, 22-24, 26, 28 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 48, 60, 62, 64 and 66 of copending Application No. 10/306,614 (PGPUB 20040101822). Although the conflicting claims are not identical, they are not patentably distinct from each other because invention of the '614 application reads on the instant claimed product.

The '614 application claims methods of using a fluorescent nanoparticle comprising a conjugated ligand, core-shell structure, as well as mercapto functional groups. (e.g. Claim 48), which the fluorescent nanoparticles read on the fluorescent nanoparticle of the instant claims.

The '614 application also claims various properties such as size, shell coverage, etc., of the fluorescent nanoparticles, which also read on the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sue Liu/
Patent Examiner, AU 1639
12/10/08